Notice of Allowability	Application No.	Applicant(s)
	09/868,177	CATES ET AL.
	Examiner	Art Unit
	Zachariah Lucas	1648
The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.		
1. This communication is responsive to the Amendment of October 14, 2005.		
2.  The allowed claim(s) is/are <u>3,5-14,20 and 21</u> .		
<ul> <li>3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some* c) None of the: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No.</li> <li>Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* Certified copies not received: <ol> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.</li> </ol> </li> <li>THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.</li> </ul>		
4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.		
5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.		
(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached		
1) hereto or 2) to Paper No./Mail Date		
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date		
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).		
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.		
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Attachment(s)	5 <b>- 1</b> November 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
1. Notice of References Cited (PTO-892)	5. ☐ Notice of Informal P	·
<ol> <li>Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statements (PTO/SB/08),</li> </ol>	6. ⊠ Interview Summary Paper No./Mail Dat 7. ⊠ Examiner's Amendn	e <u>9-26-06, 9/27/06</u> .
Paper No./Mail Date  4.  Examiner's Comment Regarding Requirement for Deposit	8. □ Examiner's Stateme	ent of Reasons for Allowance
of Biological Material	9.	

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## **DETAILED ACTION**

1. Currently, claims 3, 5-14, 20 and 21 are pending and allowed.

The claims were rejected in the prior action, mailed on February 23, 2005. In the Response, filed August 22, 2005, the Applicant amended claims 3, and 20.

In view of the arguments presented, and the amendments made to the claims, in the Response, and the Examiner's Amendment below, the rejections and objections of record are withdrawn, and the claims are allowed.

## **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael I. Stewart on September 26 and 27, 2006.

Claim 3 has been amended as follows:

the phrase "as a vaccine" has been deleted from line 7.

the phrase "prepared as described in Example 3" has been deleted from the end of the claim, and the following has been inserted in its place:

- - prepared as follows:

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(i) preparing a sterile suspension of influenza virus propagated in chicken embryos;

- (ii) inactivating the virus in the suspension with formaldehyde;
- (iii) concentrating and purifying the virus in a linear sucrose density gradient solution, where said concentrating and purifying is performed using a continuous flow centrifuge;
- (iv) chemically disrupting the purified inactivated virus using Triton X- 100, resulting in a splitantigen;
- (v) further purifying the split-antigen by chemical means;
- (vi) suspending the purified split-antigen in a sodium phosphate-buffered isotonic sodium chloride solution; and
- (vii) adding to the split-antigen solution a .05% Gelatin stabilizer and the preservative thimerosol at a 1:10,000 concentration. -.

Claim 20 has been amended to delete the term 'smmunizing' in line 1, and replace it with the phrase - - inducing an immune response in- -.

On page 1 of the application (as amended on September 24, 2003), the paragraph This application is a national phase application under 35 U.S.C. 371 of PCT/CA99/01194 filed December 16, 1999, which claims priority from US Patent Application No. 09/213,770 filed December 17, 1998."

is amended to read as follows:

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-- This application is a national phase application under 35 U.S.C. 371 of PCT/CA99/01194 filed December 16, 1999, which is a continuation-in-part of US Patent Application No. 09/213,770 filed December 17, 1998. - -

The amendments to the claims regarding the vaccine or immunizing language of claims 3 and 20 were made to overcome the rejection of record under 35 U.S.C. 112, first paragraph.

The amendment of claim 3 to add the steps for making the influenza preparation have been added such that the claims are complete in themselves as required under MPEP § 2173.05(s).

The amendment to the specification is made to correct the claim for priority to properly identify the relationships among the parent applications.

## **Drawings**

3. The corrected drawings of October 14, 2005 are accepted.

## Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z. Lucas

Patent Examiner

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